DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Atlanta District Office

60 8th Street, N.E.
Atlanta, Georgia 30309

August 10, 2000

VIA FEDERAL EXPRESS

Lennox K. Black
Chairman/Acting President
Teleflex Inc.
630 West Germantown Pike, Suite 450
Plymouth Meeting, PA 19462

WARNING LETTER
(00-ATL-55)

Dear Mr. Black:

An inspection of your firm located at 2450 Meadowbrook Parkway in Duluth, Georgia, was conducted on June 19-29, 2000, by Investigator Fulton A. Varner. Our investigator found that you continue to manufacture a variety of products utilized in anesthesiology, urology, gastroenterology, and general surgery. These products are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

Our investigator documented several significant deviations from the Quality System Regulation (QSR) as set forth in Title 21 of the Code of Federal Regulations (21 CFR), Part 820. These deviations cause the devices you manufacture and distribute to be adulterated within the meaning of Section 501(h) of the Act.

You failed to obtain sufficient information to appropriately evaluate all incoming complaints. Examples of this failure include complaints #99061 (Blakemore Tube), #20045 (Blakemore Tube), #20018 (lasertubus), and #20049 (Foley Catheter). These complaints were not submitted for any assessment as to reportability under the Medical Device Reporting requirements. The rationale used was that they were regarded as out-of-box malfunctions, detected by a medical professional, and did not involve a patient. This lack of assessment was a direct result of the complaint Decision Chart in use at the time. Although this Decision Chart was changed during the current inspection, no attempts to evaluate past complaints utilizing the new chart have apparently been made. No such documentation has been provided to this office. Our investigator was told that this type of retroactive evaluation was going to be conducted.

The investigation into complaint #20045 was deficient in that it was the second complaint involving advanced latex balloon deterioration for Lot E350610. No documentation was available of any attempt to determine the extent of the degradation problem at the time. No corrective action was initiated to address defective product that might still remain on the market. Investigator Varner was provided a Justification Letter, dated June 26, 2000, for continuing the present manufacturing process at the Lurgan facility. This letter included an analysis of the degradation complaint history of Code 2292, in addition to other analyses. This type of evaluation should have been conducted as part of the complaint review when it was received initially.

Another example of your failure to investigate was complaint #20064 (Basic Urethral Catheterization Tray). The complaint involved reported package failures consisting of holes in the tray of this sterile product. No documentation was available of any investigation performed to determine the validity of the complaint. The complaint was closed out because the complainant returned no units to Rusch for evaluation.

You have failed to conduct an appropriate analysis of incoming complaints capable of detecting product specific problems. Current complaint trending only includes a total number of complaints received during a specified time period. No specific product problems are identified to use in determining if corrective or preventive action is warranted and to identify recurring problem types.

You could not provide any statistical data or rationale to justify the current level of sampling conducted on your devices. You currently are utilizing a less discriminating inspection level on in-process, Final Product, and Post Sterilization Product samples. A review of your current product sampling plans revealed reduced sampling on such checks as cone tip bonding, seal checks, label reviews, and seal integrity. These significant inspectional checks are performed using a Special Inspection Level. These Special Inspection Levels are to be performed when large sampling risks can or must be tolerated. No rationale could be provided which would justify this current level of sampling.

You have failed to establish that your Simplastic Catheters will conform to their finished product specifications throughout the five-year expiration date placed on the product. A review of the stability data used to substantiate the current expiration date revealed several significant deficiencies. No statistical rationale was utilized in the sampling of product to assure process capability and product characteristics were challenged. No packaging integrity testing or sterility testing was included to assure the integrity of product packaging. No formalized protocol was established which defined the testing to be performed and the test acceptance criteria prior to evaluation.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. At the close of the inspection, the FDA 483 (Inspectional Observations) was issued to and discussed with Ronald J. Young, Director of Manufacturing Operations. A copy of the FDA 483 is enclosed for your review. The specific violations noted in this letter and in the FDA 483 could be

symptomatic of underlying problems in your firm's quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

We acknowledge that corrections were initiated to the investigator's observations during, and subsequent to, the inspection. We are in receipt of a response to the FDA 483 from Mr. Young dated July 5, 2000. Our review of this letter found that the response inadequately addressed the above discussed discrepancies.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory actions being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within fifteen (15) days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. Your response to this letter should be sent to Philip S. Campbell, Compliance Officer, at the address noted in the letterhead.

Sincerely yours,

Ballard H. Graham, Director
Atlanta District

Enclosure

cc: David Emm, President
Rusch, Inc.
2450 Meadowbrook Parkway
Duluth, Georgia 30136